

REMARKS

Surrender of original patent

The original Letters Patent has been surrendered and its receipt acknowledged in the communication of December 19, 2003.

Consent of Assignee

The consent of the assignee was filed on February 28, 2003.

Status of claims

Claims 1-36 and 38-47 are pending. Claims 37 and 48 have been cancelled.

Current amendments to the claims

Claim 35 has been amended to provide that the chambers are sterile and adjacent each other. This is clearly disclosed in figure 2. Claim 35 has also been amended to recite means for sterile transfer of a fluid to or from a chamber, which is language permitted by 35 USC 112, sixth paragraph, and reads on access ports 13 and 15 and their equivalents.

Claim 38 has been amended to recite a locking element that selectively holds the container in a predetermined orientation. This generic recitation is disclosed in the specification by the preferred locking plate 36.

Claims 40 and 42 have been amended to be consistent with claim 38 by reciting the locking plate specifically.

Claim 43 has been amended to recite the location of the bridge as being at the top portions of the chambers and an access port also near the top of at least one of the chambers. The access ports allow sterile transfer of a liquid to at least one of the chambers independently of the other of the chambers from the exterior of the container. This structure including the generic "access port" that maintains sterility is clearly disclosed at column 2, lines 59 *et seq.* and in figure 2.

Amendments to the claims on February 28, 2003

Claim 32 was amended to provide that the first and second chambers are adjacent each other. This feature is disclosed in figure 2. Claim 32 was also amended to recite that the bridge allows transfer of a fluid when the container is in a predetermined orientation. This is disclosed in figure 4b. Claim 32 was amended to recite that the holder is broadly effective to orient the container in the predetermined

orientation. The frame 32 is a specific disclosure of a holder, and figure 3b shows the holder orienting the container in the predetermined orientation. Claim 32 was amended to add the step of adding a physiological product to one of the chambers. This is disclosed at column 2, beginning at line 50. Claim 32 was also amended for grammatical reasons (e.g., plural to singular) and to change "position" to "orient." These changes are stylistic and are clearly supported by the disclosure.

Claims 33 and 36 were amended to delete the word "removable." A lid is disclosed as element 11, and there was no requirement that it be removable or not.

Claim 35 was amended for clarity to recite the top portions of the first and second chambers, respectively, as the first top portion and the second top portion. Claim 35 was also amended to add the recitation of a means for maintaining sterility and the step of placing a physiological fluid in one of the chambers. The means for maintaining sterility is language permitted by 35 USC 112, sixth paragraph, and reads on the ports 13 and 15 and their equivalents.

Claims 38 and 43 were amended to add the step of placing the physiological product in one of the chambers. This is clearly supported by the specification at column 2, beginning at line 50.

Claim 39 and 42 were amended for grammatical purposes to change a "centrifuge rotor" to a "rotor of said centrifuge."

Claim 47 was amended to change "container" to "method" to conform to the parent claim.

Claim 48 was added, but this has now been canceled.

Amendments to claim 42 on May 14, 2003

Claim 42 was amended to remove the limitation that the locking plate must engage the frame. While this is the preferred embodiment, it is submitted that the original disclosure would have disclosed the generic recitation to one of ordinary skill in the art.

Amendments to claim 38 on July 3, 2003

Claim 38 was amended to recite "sterile access" instead of access "to maintain sterility." This is stylistic and is fully supported by the disclosure at column 4, lines 4-5.

Rejections

The interviews with Examiner Cooley on August 19, 2003, December 19, 2003, and January 2, 2004 are noted. At the interviews of August 19, 2003, and January 2, 2004, the references to McFarland, Raccuglia, Crippa and Onishi were discussed. The reference to Li was also discussed at the interview of January 2, 2004. The interview of December 19, 2003, was limited to discussion of the formal requirements for amendments in reissue cases. The substance of the discussions regarding the prior art at the interviews is summarized below. Reconsideration of the rejections is again requested.

Claim 35 now clearly distinguishes over Raccuglia, McFarland, Onishi and Crippa in the recitation of chambers with adjacent top portions and means for providing sterile transfer near the tops of at least one of the chambers. Raccuglia does not have adjacent chambers, and McFarland, Onishi and Crippa do not provide sterile access to the chambers by structure located at the upper parts of the chambers.

In connection with claim 35, it is submitted that nothing in McFarland is equivalent to the recited means for sterile transfer of a liquid. MPEP §2183 sets forth four ways for assessing equivalence, and the claimed element differs from that shown in McFarland in all four ways. The function specified in claim 35 is that of "sterile transfer of a liquid to or from at least one of said chambers independently of the other of said chambers," and the corresponding structure disclosed is that of an access port with an opening that is covered by a membrane capable of receiving a syringe to inject or withdraw fluids. The structure shown in figures 1 and 2 of McFarland is simply a tubular connector 32, and in figure 3 is a header 62, neither of which allows introduction or withdrawal of fluids to at least one of the chambers independently of the other. Thus, McFarland fails to show structure capable of accomplishing the recited function. It is submitted further that neither the valve 34, nor the connector 32, nor the header 62 could be substituted for the structure disclosed in the instant application corresponding to the recited means. Application of the connector or header to the disclosed container would be nonsensical, and providing the storage tank of McFarland with the access ports designed to receive medical instruments such as syringes would completely ruin the McFarland storage tank for its intended purpose of pressurizing the tanks with air.

Still further, it is submitted that there are substantial differences between the structure of McFarland that supplies connectors 32 and header 64, on the one hand, and the structure corresponding to the recited means, on the other, in that the McFarland structure is incapable of allowing transfer to or from one of the chambers independently of the others. Finally, the recited element is clearly not the structural equivalent of that shown in McFarland because they do not perform the same function and do not accomplish the same result.

Similarly, nothing in Crippa, Onishi, and Li is equivalent to or would have led one of ordinary skill in the art to the invention. These containers are not designed to maintain sterility, and any addition or removal of fluids destroys sterility because the lids must be removed during the process. This contrasts significantly with the claimed subject matter where ports are provided for permitting sterile access to the chambers. Thus, the recited structures are not equivalent to the structures shown in Crippa, Onishi, and Li because the structures of those patents cannot perform the recited function of sterile transfer. For this reason they are clearly not interchangeable. There are clearly substantial differences between a lid that cannot maintain sterility and the recited structure that does. And, the lids of Crippa, Onishi, and Li are clearly not the structural equivalents of the recited structure because the Crippa, Onishi, and Li structures do not maintain sterility.

In connection with claim 38, it is noted that Raccuglia does not teach the recited locking element that holds the container in a desired orientation.

Claim 43 now clearly distinguishes over the art of record, particularly Crippa, McFarland, and Onishi by the recitation of a bridge at the top portions of the two chambers and an access port near the top of at least one of the chambers that allows sterile transfer to a chamber from the exterior of the container. McFarland and Onishi have nothing to do with physiological fluids, and nothing in the art of record would have led one of ordinary skill in the art to the use with physiological fluids as claimed. Crippa does not have or suggest structure to allow sterile transfer to a chamber from the exterior of the container, and the lids of both Onishi and Crippa do not allow sterile access to chambers.

Accordingly, it is submitted that this application is in condition for allowance, and an early indication thereof is respectfully requested. The examiner is invited to contact the undersigned if any matter remains outstanding.

All necessary extensions of time are requested. Please charge any necessary fees and credit any excess to deposit account 50-1088.

Respectfully Submitted,
CLARK & BRODY



Conrad J. Clark
Reg. No. 30,340

Suite 600
1750 K Street NW
Washington, DC 20006
202-835-1111
202-835-1755 (fax)
January 7, 2004